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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,859	11/05/2001	Paul O. Sheppard	97-75C1	5991

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/011,859	SHEPPARD ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-9 and 14-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/02, 9/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, with species 85-1078 in the reply filed on 9/27/2004 is acknowledged.

Claims 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/27/2004.

Information Disclosure Statement

Applicants have submitted two information disclosure statements, on 3/14/2002 and 9/27/2004. Both have been considered, and the signed forms PTO-1449 are enclosed. It is noted that the relevance of references A2-A11 and A17 cannot be assessed; the references are nucleic acid sequences, and no indication of relevance or alignment to the disclosed sequences has been provided. References A12-A16 are descriptions of the source of various cDNA libraries; the relevance of such to the instant disclosure is not clear to the Examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 5 are rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 6,395,890 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claims are coextensive in scope, as nucleotides 70-1062 of SEQ ID NO: 3 encode residues 24-354 of SEQ ID NO: 2.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO: 1 or fragment thereof that is useful as a hybridization probe, does not reasonably provide enablement for nucleic acids that encode the protein of SEQ ID NO: 2, nor for expression vectors or method of producing protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed polynucleotides as drawn to SEQ ID NO: 1 are useful as a hybridization probe for 6q22.1. Applicants have made of record two papers which support this assertion, such that utility is established for the nucleic acids of SEQ ID NO: 1 (Gladwin et al., Human Molecular Genetics 6(1):123-127, 1997, and Braverman et al., Nature Genetics 15:369-376, 1997). The argument that the claimed nucleic acids are useful for such mapping does not apply to the remainder of the nucleic acid claims, which are drawn to a nucleic acid *encoding* a protein, as there is no utility for encoding or producing such protein, for reasons discussed below, and similarly do not apply to the protein itself, as proteins may not be used for chromosomal mapping.

It is disclosed at page 39 of the specification that the polypeptide is "characterized by its proliferative or differentiating activity, or ability to induce specialized cell functions, or by the ability to bind specifically to an anti-zCTGF4 antibody." These characterizations are apparently based on the disclosure at page 12 that expression was detected in testis, trachea, bone marrow and kidney tissue, taken with the identification of particular types of domains in the protein. No specific function or activity is demonstrated for the protein.

zCTGF4 is represented by SEQ ID NO: 2 (protein) and SEQ ID NO: 1 (nucleic acid). SEQ ID NO: 3 is a degenerate sequence that also encodes SEQ ID NO: 2. SEQ ID NO: 1 is only 52.8% identical to the nucleic acid encoding CTGF as disclosed by Grotendorst et al., U.S. Patent Number 5,408,040, cited by applicants. No specific function or activity is demonstrated for the protein. The skilled artisan would not consider that 52.8% homology would be predictive of function, and therefore of utility. It is noted that applicants argued in the parent case that the IGF-like domain of zCTGF4 is 75% identical to that of CTGF, and the sulfated glycoconjugate binding motif domain is 60% identical with CTGF. Even these more limited comparisons of particular portions of the protein would not be considered by the skilled artisan to be predictive of function, and consequently biological activity. As no function has been established for zCTGF4, and there is no disclosure of the functional significance of these domains in CTGF, the higher similarity in these regions bears no particular significance, that is, cannot be relied upon to make a case that there is more likely to be functional similarity. More to the point however, the assertion that the disclosed zCTGF4 has biological activities similar to CTGF cannot be accepted in the absence of supporting evidence, because the relevant literature

does not support the assertion that assignment to the CTGF family of proteins is predictive of function. For example, Brigstock (Endocrine Reviews 20(2):189-206, April 1999) teaches that the CCN family of proteins includes CTGF, cyr61, Elm1/WISP1, Nov, CTGF-3, WISP-2 and -3, and others, and that classification in this family is not predictive of function. At page 202, Brigstock states that "As the (CCN) family has growth, so has its spectrum of biological properties. In fact, the range of activities within the CCN family is now so broad that their classification on a functional basis is difficult, if not impossible. While they have been categorized by several investigators as ECM or extracellular signaling molecules, this is certainly not a distinguishing feature of the CCN family nor particularly unexpected for modular proteins."

Therefore, one cannot rely upon structural similarity alone to determine functionality, the specification fails to teach the skilled artisan any use for the claimed polynucleotides to make biologically active zCTGF4, or for the protein itself, without resorting to undue experimentation to determine what the specific biological activities of the zCTGF4 are. Thus, with the exception of the nucleic acid of SEQ ID NO: 1 the specification fails to teach how to use the claimed polynucleotides, vectors, cells or method. It is noted that a generic claim to a vector (*not* an *expression* vector) comprising SEQ ID NO: 1 would be found to be enabled, as would host cells comprising such a vector. Until some actual and specific activity can be attributed to the protein identified in the specification as zCTGF4 protein or the polynucleotides encoding it, one would not know how to use the claimed matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite due to an unpaired bracket at part (b), prior to the word "encoding".

Claim 7 is indefinite because claim 1, from which it depends uses the singular "polynucleotide molecule", whereas claim 7 uses the plural "molecules", for which there is no antecedent basis. Further, if applicants intend the plural, the claim would be indefinite as it is not clear how many such molecules are envisioned.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pennica et al., PNAS 95:14717, cited by applicants, disclose the sequence of a gene they designate WISP3. WISP3 is 99.8% identical to SEQ ID NO: 1. The reference was published in December, 1998.

Hurvitz et al., Nature Genetics 23:94, cited by applicants, discloses that mutations in WISP3 cause progressive pseudoheumatoid dysplasia. The reference was published in September, 1999.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner

1/7/2005